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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,179	10/05/2005	Marcus J Seewald	050696-US	7828
30234 7590 03/18/2009 LAW OFFICES OF KARL HORMANN 86 SPARKS STREET CAMBRIDGE, MA 02138				
EXAMINER				
GWARTNEY, ELIZABETH A				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
03/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,179

Applicant(s)

SEEWALD, MARCUS J

Examiner

Elizabeth Gwartney

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The Amendment filed 11/28/2008 has been entered. Claim 18 has been added. Claims 5-18 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson ("Fermented Meat Products" in Encyclopedia of Food Microbiology) in view of Rader ("Folic Acid Fortification, Folate Status, and Plasma Homocysteine") and as evidenced by Kerry et al. ("Quality control of fermented meat products" in Meat Processing-Improving Quality).

Regarding claims 5-7, 9-10 and 18, Robinson discloses a method of making a semi-dry sausage, comprising the steps of providing minced beef, pork and pork fat, mixing the minced meat with additives including pepper, garlic, sugar, and cardamom, stuffing the mixture into

natural or artificial casings, and storing the sausage for 9-23 days at a relative humidity of 58 - 95% and a temperature of 12-30° C (p. 744/Manufacture of Fermented Sausages/P1, p. 747/Table 1/Dry Sausage)

While Robinson discloses the addition of additives, the reference does not explicitly disclose adding from about 4 mg. to about 25 mg. per kilogram of meat a material selected from the group consisting of folic acid and folate.

Rader teaches that folic acid is a known nutritive additive in foods (Abstract). Rader teaches that folic acid fortification of food is intended to increase intake of folic acid among humans and reduce the risk of a pregnancy affected by a neural tube birth defect (NTD) and vascular disease (Abstract). Rader teaches that the addition of folic acid to enriched cereal-grain products became mandatory in the U.S. on January 1, 1998 at a level of 140 µg folic acid/100 g cereal-grain product (p. 2466S/Introduction).

Given that the improvement of the nutritional value of meat products has been tried for years (as evidenced by Kerry et al. - p. 382/Section 18.9.2), it would have been obvious to one of ordinary skill in the art to fortify the semi-dry sausage of Robinson with folic acid or folate, as taught by Rader. A skilled artisan would do so in order to increase the intake of folic acid or folate acid and reduce the risk of NTD-pregnancies and vascular disease.

While Rader teaches that folic acid is added to cereal-grain at a level of 140 µg folic acid/100 g, it is the examiner's position that folic acid concentration is a result effective variable because changing it would clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215

(CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate folic acid concentration, including that within the scope of the present claims, so as to produce desired end results.

Regarding claim 8, modified Robinson discloses all of the claim limitations as set forth above but the reference does not disclose that the material is added in a substantially uniform distribution during the step of adding spice. A skilled artisan would know to add ingredients to a food mixture in a uniform distribution in order to produce a homogenous product. It would have been obvious to one of ordinary skill in the art at the time of the invention to have added the material to the sausage of Robinson in a uniform distribution for the purpose of making a product homogenous in flavor, texture and nutritional value.

Regarding claim 11, modified Robinson discloses all of the claim limitations as set forth above but the reference fails to disclose the step of washing the sausage in water. A skilled artisan would know to wash a stuffed sausage product prior to ripening in order to remove undesirable bacteria and debris. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have washed the sausage of modified Robinson with water to remove undesirable debris and prevent contamination for undesirable bacteria, yeast, and molds.

Regarding claim 12, modified Robinson discloses all of the claim limitations as set forth above and that yeast and molds commonly develop on the surface of the fermented sausage during ripening (p. 745/Manufacture of Fermented Sausages/P2). Further, Robinson discloses that to ensure reliability of the quality of fermented meat products, starter cultures are used (p. 745/Desirable Flora/P3). As starter cultures, molds such as *Penicillium nalgioense*, *P.*

chrysogenum or *P. camemberti* are added to the surface of the sausage casing (p. 746/Starter Cultures for Fermented Sausages/P1). While Robinson does not explicitly disclose that the mold is dissolved in water, it would have been obvious to one of ordinary skill in the art at the time of the invention to have treated the exterior of the sausage with a mold starter culture dissolved in water to ensure an even distribution of the culture over the exterior of the entire sausage casing.

Regarding claims 13-17, modified Robinson discloses all of the claim limitations as set forth above. Robinson also discloses storing the sausage for 9-23 days with an initial 18-48 hours at 58-95% humidity and a temperature of 20-30°C and thereafter stored at a relative humidity of 75-80% and a temperature of 12-15°C (p. 747/Table 1/Dry sausage).

While Robinson discloses storing the sausage for a total of 9-24 days with a 48 hour period of fermentation at a relative humidity of 58-95% and a temperature of 20-30°C (p. 747/Table 1/Dry sausage), the reference does not disclose a period of fermentation lasting 3 days or an additional two days at a relative humidity of about 88% and temperature of 22°C.

As flavor intensity, flavor character and fermentation rate are variables that can be modified, among others, by adjusting the time, humidity and temperature of sausage storage within the range disclosed by Robinson, the precise storage time, humidity, and temperature would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, storage time, humidity and temperature cannot be considered critical within the range disclosed by Robinson. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized by routine experimentation the time, humidity, and temperature of each phase of sausage storage to obtain the desired balance between fermentation rate and flavor intensity and

character. (In *re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In *re Aller*, 105 USPQ 223).

Response to Arguments

5. Applicant's arguments filed 11/28/2008 have been fully considered but they are not persuasive.

Applicants explain that the claims of the present invention are not directed to what folic acid or folate added to sausage does to the health of the consumer rather, the consequences in terms of a consumer's health are inherent in the consumption of folic acid. Applicants argue that it is not obvious that adding folic acid to minced sausage meat mixtures yields an end product more quickly and further having superior taste or flavor, consistency and storability.

Here, "obviousness under 103 is not negated because the motivation to arrive at the claimed invention as disclosed by the prior art does not agree with appellant's motivation", *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990), *In re Tomlinson*, 150 USPQ 623 (CCPA 1966).

Applicants argue that Rader is nonanalogous art. Applicants find that the art of treating cereal grain products with folic acid is distinct from the art of sausage making.

In response to applicant's argument that Rader is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977

F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Rader is in the field of applicant's endeavor, namely, improving the value of food products.

Applicant argues that the addition of from 4 to 25 mg. of folic acid per kg of raw sausage constitutes an optimum because the reduction of folic acid in the sausage, rather than proceeding linearly, follows a special functional curve.

Because there is substantial evidence to support determination of a prima facie case of obviousness over each of the applied prior art references, the burden of proof was properly shifted to the applicants to rebut the prima facie case by presenting persuasive arguments or evidence (e.g. unexpected results). *In re Mayne*, 104 F.3d 1339, 1343, 41 USPQ2d 1451, 1455 (Fed. Cir. 1997). ("With a factual foundation for its prima facie case of obviousness shown, the burden shifts to applicants to demonstrate that their claimed fusion proteins possess an unexpected property over the prior art.")

Unexpected results must be established by factual evidence; mere argument or conclusory statements in the specification do not suffice. *In re Geisler*, 116 F.3d 1465, 1470, 43 USPQ2d 1362, 1365 (Fed. Cir. 1977) (quoting *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)). Unexpected results must be established by comparing the claimed invention against the closest prior art. *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("[A]n applicant relying on comparative tests to rebut a prima facie case of obviousness must compare his claimed invention to the closest prior art."); accord *In re Merchant*, 575 F.2d 865, 869, 197 USPQ 785, 788 (CCPA 1978). In this case, applicant has not provided evidence that the claimed range of folic acid or folate results in an unexpected property.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794